IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re application of:			
Joseph R. BYRUM *et al.*		Art Unit:	1635
Appln. No.:	09/199,129	Examiner:	K. A. LACOURCIERE
Filed:	November 24,1998	Atty. Docket:	38-21(15075)B
Title:	Nucleic Acid Molecules and Other Molecules Associated with Plants		

APPELLANTS' BRIEF

Commissioner for Patents
Washington, DC 20231

Sir:

This is an Appeal from the Final Rejection of all claims pending in the above-identified patent application. A Notice of Appeal was filed on May 6, 2002. The statutory fee of $320.00 for submitting this Brief is included in our attached Check No. **201435**. *This Brief is submitted in triplicate.*

1. Real Party in Interest

The real party in interest is Monsanto Company, a Delaware corporation with offices at 800 North Lindbergh Boulevard, St. Louis, Missouri 63167. Monsanto Company is a subsidiary of Pharmacia Corporation, located at 100 Route 206 North, Peapack, New Jersey 07977.

2. Related Appeals and Interferences

The Applicants are unaware of any Appeals or Interferences related to this Appeal.

3. Status of Claims

Claims 1 and 4-12 are pending. Claims 2, 3, and 13-17 have been cancelled without prejudice. Claims 1, 4, and 8 are independent. Claims 1 and 4-12 stand finally rejected under 35 U.S.C. §§ 101 and 112, first paragraph. Applicants appeal all of the rejections of claims 1 and 4-12.

4. Status of Amendments

Applicants have filed an Amendment after Final Rejection concurrently herewith canceling claims 2, 3, and 13-17. The amendment is intended to clarify the issues with respect to the restriction requirement requiring cancellation of claims drawn to a non-elected invention.

5. Summary of Invention

The invention is directed to nucleic acid molecules that encode soybean proteins or fragments thereof, transformed plants incorporating these molecules, and methods for determining the level of pattern of expression of a protein in plants incorporating these molecules. The claimed nucleic acid molecules were derived from a cDNA collection prepared from various soybean tissues. *Specification* at page 30, line 2 through page 34 line 16, and Examples 1-2. More particularly, the present invention is directed to a substantially purified nucleic acid molecule encoding a soybean protein or fragment thereof comprising a nucleic acid sequence of SEQ ID NO: 1, a transformed plant incorporating SEQ ID NO: 1, and methods of using SEQ ID NO: 1.

6. Issues

The issues on Appeal are:

(a) whether claims 1 and 4-12 are unpatentable under 35 U.S.C. § 101 for allegedly being unsupported by a specific asserted utility or a well established utility;

(b) whether claims 1 and 4-12 are unpatentable under 35 U.S.C. § 112, first paragraph for alleged lack of enablement because the claimed invention purportedly lacks utility; and

(c) whether claims 1 and 4-12 are unpatentable under 35 U.S.C. § 112, first paragraph for alleged insufficiency of written description.

7. Grouping of Claims

Independent claims 1, 4, and 8 remain in this case. Claim 5 is dependent on claim 4, and claims 9-12 depend from claim 8. A copy of the currently pending claims on appeal is attached hereto as Appendix A.

8. Argument

A. Summary of Applicants' Position

As the Supreme Court said in *Brenner v. Manson*, the "basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility . . . where specific benefit exists in currently available form." 383 U.S. 519, 534-35, 148 U.S.P.Q. 689, 695 (1966). Applicants have met their part of the bargain – they have disclosed nucleic acid molecules which, in their current form, provide at least one specific benefit to the public, *e.g.*, the ability to identify the presence or absence of a polymorphism in a population of soybean plants. This benefit is specific, not vague or unknown, and it is a "real world" or substantial benefit. Because the claimed nucleic acid molecules provide at least this benefit, they satisfy the utility requirement of 35 U.S.C. § 101. Because the specification teaches how to make and use the claimed nucleic acids for the disclosed utilities, the enablement requirement of 35 U.S.C. § 112 has been met.

Furthermore, Applicants have provided an adequate written description of the claimed nucleic acid molecules that demonstrates Applicants' possession of the claimed invention. The genus of claimed nucleic acid molecules, *i.e.*, the genera of nucleic acid molecules comprising the nucleic acid sequences of SEQ ID NO: 1, has been described by the recitation of a common structural feature, *i.e.*, the nucleotide sequence of SEQ ID NO: 1, which distinguishes molecules

in the claimed genus from molecules not in the claimed genus. Because the specification demonstrates that Applicants had possession of the invention, and have provided an adequate description of the claimed genus of nucleic acid molecules, the specification satisfies the written description requirement of 35 U.S.C. § 112, first paragraph.

B. The Claimed Nucleic Acids Have Legal Utility

Claims 1 and 4-12 were erroneously rejected under 35 U.S.C. § 101 as allegedly not supported by either a "specific asserted utility" or a "substantial utility." *Final Action mailed February 7, 2002* (Paper No. 14) ("Final Action") at pages 3-5. More particularly, the Final Action asserts that the "disclosed uses of the nucleic acids (and proteins encoded by said nucleic acids) are not specific and are generally applicable to any nucleic acid and/or protein. . . Further, the claimed nucleic acid (and proteins encoded by said nucleic acids) are not supported by a substantial utility because no substantial utility has been established for the claimed subject matter." *Id.* at page 4.

This analysis misstates the nature of the asserted uses, ignores disclosed utilities, and misapplies the doctrine of "practical utility" developed by the courts after *Brenner v. Manson.* The "threshold for utility is not high: An invention is 'useful' under section 101 if it is capable of providing some identifiable benefit." *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1366, 51 U.S.P.Q.2d 1700, 1702 (Fed. Cir. 1999), *citing Brenner v. Manson*, 383 U.S. 519, 534 (1966). Furthermore, an invention need only provide one identifiable benefit to satisfy 35 U.S.C. § 101. *See Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 958, 220 U.S.P.Q. 592, 598 (Fed. Cir. 1983) ("when a properly claimed invention meets at least one stated objective, utility under section 101 is clearly shown").

The courts have expressed a test for utility that hinges on whether an invention provides an "identifiable benefit." *Juicy Whip*, 185 F.3d at 1366, 51 USPQ.2d at 1702. For analytical purposes, the requirement for an "identifiable benefit" may be broken into two prongs: (1) the

invention must have a specific, *i.e.*, not vague or unknown benefit, *In re Brana*, 51 F.3d 1560, 1565, 34 U.S.P.Q.2d 1436, 1440 (Fed. Cir. 1995); and (2) the invention must provide a real world, *i.e.*, practical or "substantial" benefit. *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1563, 39 U.S.P.Q.2d 1895, 1899 (Fed. Cir. 1996). A corollary to this test for utility is that the invention must not be "totally incapable of achieving a useful result," *i.e.*, the utility must not be incredible or unbelievable. *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571, 24 U.S.P.Q.2d 1401, 1412 (Fed. Cir. 1992).

(1) The Claimed Nucleic Acid Molecules Provide A Specific Benefit, *i.e.*, They Have Specific Utility

The Examiner acknowledges that the specification describes multiple utilities for the present invention, including "probes for assisting in the isolation of full-length cDNAs or genes which would be used to make protein and optionally further usage to make the corresponding antibodies, gene mapping, isolation of homologous sequences, detection of gene expression such as in Northern blot analysis, molecular weight markers, chromosomal markers, and for numerous other generic genetic engineering usages." *Final Action* at page 4. In addition to the utilities described by the Examiner (quoted above), the invention is useful for detecting the presence and level of mRNA in a sample; identifying polymorphisms; obtaining promoters and other flanking genetic elements to such molecules; determining the location of a corresponding DNA sequence on a genetic map; isolating related nucleic acid and protein molecules; and conducting plant transformation or transfection; etc. (*see, e.g., Specification* beginning at page 30, under heading "Uses of the Agents of the Invention").

The specification also discloses additional utilities for the claimed nucleic acid molecules, including introduction of the claimed nucleic acid molecules into a plant or plant cell (either as sense or antisense inhibitors), which can then be used to screen for compounds such as a herbicide. Specification at page 75, line 11 through page 78, line 22. For example, a

compound can be provided to both an antisense plant and a control plant (no antisense) and the effect of the compound on the plant can be monitored. Such a screen is analogous to a cell-based assay, which has a legally sufficient utility.[1] Thus, the use in such a screen of a plant or plant cell having an introduced claimed nucleic acid molecule is a legally sufficient utility. Other utilities disclosed in the specification include use of the claimed nucleic acid molecules to measure the level of mRNA in a sample,[2] and use as molecular markers.[3]

Applicants have asserted in the specification that the claimed nucleic acid molecules provide identifiable benefits. Any of these utilities alone is enough to satisfy Section 101. Because Applicants need only establish a single utility to satisfy 35 U.S.C. § 101, and they have done so in the present case, the premise of the rejection under Section 101 is incorrect, and the rejection should be reversed.

(a) Identifying the Presence or Absence of a Polymorphism

More particularly, one of the utilities disclosed in the specification is use of the claimed nucleic acid molecule to identify the presence or absence of a polymorphism. The Examiner argues that this utility, like all of the asserted utilities, is not specific or substantial, but does not

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[1] *See, e.g.*, MPEP § 2107 at page 2100-32.

[2] It is standard practice to screen populations of nucleic acids with EST sequences, often attached to a microarray, without characterizing each and every target mRNA. Knowing that the gene corresponding to the claimed nucleic acid molecules is expressed under certain conditions or in certain tissues or at certain levels is in itself useful. For example, such information is useful to detect expression changes in traits of interest, *e.g.*, drought stress. Contrary to the Examiner's assertions, this use is not using the claimed nucleic acid molecules to identify a "'real world' context of use." Final Action at page 5. It is a use of the claimed nucleic acid molecules in a real world context.

[3] One can use the claimed nucleic acid molecules to determine location of a corresponding DNA sequence on a physical map or genetic map location without knowing anything beyond the claimed sequence. The use of molecular markers is a practical activity in the development of nutritionally enhanced or agriculturally enhanced crops. Such markers are useful in, for example, genetic mapping or linkage analysis, marker-assisted breeding, physical genome mapping, transgenic crop production, crop monitoring diagnostics, and gene identification and isolation. As more markers are identified, genetic maps will become more detailed and it will be easier for plant breeders to breed for particular traits.

provide any support (legal or factual) for the proposition that detection of polymorphisms is not a legal utility.

Many of the disclosed utilities in this case, including the detection of polymorphisms, are directly analogous to the utilities of a microscope, *i.e.*, the claimed nucleic acid molecules may be used to locate and measure nucleic acid molecules within a sample, cell, or organism. However, the fact that, *e.g.*, a new and nonobvious microscope or screening assay can be used for learning about products or processes does not lessen the fact that such "tools" have legal utility. "Many research tools such as gas chromatographs, screening assays, and nucleotide sequencing techniques have clear, specific and unquestionable utility (*e.g.*, they are useful in analyzing compounds)." MPEP § 2107 at page 2100-33.

Use of the claimed nucleic acid molecules to detect the presence or absence of polymorphisms is no more legally insufficient than using a gas chromatograph to analyze the chemical composition of a gas – such use determines information about the gas, not the gas chromatograph. Even if the gas chromatograph detects the absence of a particular chemical element in the gas, that finding does not obviate the utility of the gas chromatograph itself. Information has been obtained about the gas.[4] Likewise, the claimed nucleic acid molecules have utility even if the absence of a particular polymorphism is detected. Indeed, the absence of a polymorphism usefully demonstrates that the two (or more) populations being compared share a common genetic heritage.

The claimed nucleic acid molecules have been asserted to work for a specific, *i.e.*, not vague or unknown benefit, to identify the presence or absence of a polymorphism. This benefit is immediately realized directly from the use of the claimed nucleic acids, not from the use of

[4] For example, gas sampled from crude oil may be analyzed by gas chromatography for the presence or absence of chlorine, which is toxic to catalysts used in gasoline refining even in very low concentrations. The absence of a peak at the molecular weight of chlorine indicates the absence of chlorine in the sample being tested, thereby providing useful information (no chlorine is present, therefore the catalyst will not be destroyed) to the refinery manager. *See, e.g.*, U.S. Patent No. 6,133,740 entitled "Chlorine Specific Gas Chromatographic Detector."

other molecules. Such a proven use that provides an acknowledged known benefit to the public satisfies the utility requirement of 35 U.S.C. § 101.

(b) Probes for Other Molecules or Source for Primers

Other uses for the claimed nucleic acid molecules are as probes for other molecules or as a source of primers. The Examiner suggests that these uses are not legal utilities because the specification has not disclosed any specific nucleic acid molecule that can be identified using the claimed nucleic acid molecules. Final Action at page 11. This is not correct. The specification discloses that the claimed nucleic acid molecules can be used to isolate nucleic acid molecules of other plants and organisms such as alfalfa, *Arabidopsis*, *Brassica*, barley, cotton, oat, rice, etc.[5] *Specification* at page 30, line 10 through page 31, line 2. The Examiner has not provided any evidence that would reasonably suggest that this cannot be done, and thus has not met the burden of proof required to establish a utility rejection. *See In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995). *Accord In re Gaubert*, 524 F.2d 1222, 1225-26, 187 U.S.P.Q. 664, 666 (CCPA 1975); *In re Langer*, 503 F.2d 1380, 1391, 183 U.S.P.Q. 288, 297 (CCPA 1974).

An illustrative example of a molecule that can be isolated using the claimed nucleic acid molecules is the promoter of the gene corresponding to the claimed nucleic acid molecules. Further, Applicants have specifically disclosed that one use of the claimed nucleic acid molecules is to initiate a chromosome walk. *Specification* at page 31, line 22 through page 33, line 3. Nonetheless, the Examiner attempts to undermine the existing utilities by stating that the asserted utilities are "not specific and are generally applicable to any nucleic acid and/or protein." *Final Action* at page 4. The Examiner's application of this standard ignores the

[5] Furthermore, one skilled in the art of hybridization and amplification understands how to design and utilize probes and primers to target a sequence of interest, and therefore it is not necessary for Applicants to provide a laundry list of each and every nucleic acid molecule that can be identified using the claimed nucleic acid molecules.

presently disclosed utilities and contravenes well-established doctrines of utility developed in the courts. In short, the Examiner suggests that the asserted utilities are legally insufficient simply because other molecules can be used for the same purpose. This position is wrong as a matter of law – there is no requirement of exclusive utility in the patent law. *See Carl Zeiss Stiftung v. Renishaw PLC*, 945 F.2d 1173, 1180, 20 U.S.P.Q.2d 1094, 1100 (Fed. Cir. 1991) ("An invention need not be the best or the only way to accomplish a certain result...").

Such an argument would imply that a new golf club has no legal utility because other golf clubs can be used for the same purpose, *i.e.*, hitting golf balls. Such a position must be rejected as it requires reading "into the patent laws limitations and conditions which the legislature has not expressed," a practice condemned by the Supreme Court. *See Diamond v. Chakrabarty*, 447 U.S. 303, 308, 206 U.S.P.Q. 193, 196 (1980), *quoting United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 199, 17 U.S.P.Q. 154, 162 (1933). Thus, it must be the case that a utility, generic to a broad class of molecules, does not compromise the specific utility of an individual member of that class.

Moreover, it is factually incorrect that this use is not "specific" to the claimed nucleic acids. The claimed nucleic acid molecules provide a particularly appropriate and demonstrably useful starting point for a walk to isolate a promoter that is active in leaves at the time of anthesis. Isolation of such a promoter would be desirable and particularly useful because it allows expression of proteins at that important developmental state, including proteins that provide disease resistance. Because the claimed nucleic acid molecules were isolated from leaves, they provide an appropriate starting point for isolating a promoter active in leaves. *Specification* at page 30. A random nucleic acid molecule does not provide an equally good starting point to isolate such a promoter. Furthermore, even if a random nucleic acid molecule provided a <u>better</u> starting point than the claimed nucleic acid molecules, it would not obviate the utility of the claimed nucleic acid molecules. An invention may be "less effective than existing

devices but nevertheless meet the statutory criteria for patentability." *Custom Accessories, Inc. v. Jeffrey-Allan Indus.*, 807 F.2d 955, 960 n.12, 1 U.S.P.Q.2d 1196, 1199 n.12 (Fed. Cir. 1986).

Applicants note that the claimed nucleic acid molecules have many utilities. Some of these utilities may be common to a broader class of molecules. For instance, nucleic acid sequences may generally be used to identify and isolate related sequences. However, when used in this manner, the result is not generic. Rather, the claimed nucleic acid molecules will identify a unique subset of related sequences. This subset of related sequences is specific to the claimed sequences and cannot be identified by any generic nucleic acid molecule. For example, a random nucleic acid molecule would not provide this specific utility. Referring again to the golf club analogy, the club is still generically hitting a golf ball, but is uniquely designed to hit the ball in a manner that is distinct from other clubs. Once again, Applicants assert that the claimed nucleic acid sequences exhibit the requisite utility under 35 U.S.C. §101.

The Examiner also notes that the credibility of the presently asserted utilities has not been assessed. *Final Action* at page 5. However, this is precisely the issue that the courts have emphasized in evaluating the adequacy of an asserted utility. Utility is determined "by reference to, and a factual analysis of, the disclosure of the application." *In re Ziegler*, 992 F.2d 1197, 1201, 26 U.S.P.Q.2d 1600, 1603 (Fed. Cir. 1993), *quoting Cross v. Iizuka*, 753 F.2d 1040, 1044, 224 U.S.P.Q. 739, 742 (Fed. Cir. 1985). The Examiner "has the initial burden of challenging a presumptively correct assertion of utility in the disclosure." *In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995). The utilities asserted in the specification must be accepted as factually sound unless the Patent Office cites information that undermines the credibility of the assertion. *Id.* The Examiner "must do more than merely question operability – [he] must set forth factual reasons which would lead one skilled in the art to question the objective truth of the statement of operability." *In re Gaubert*, 524 F.2d 1222, 1225-26, 187 U.S.P.Q. 664, 666 (CCPA 1975) (emphasis in original).

(2) The Claimed Nucleic Acid Molecules Provide Practical, Real World Benefits, *i.e.*, They Have Substantial Utility

The Examiner also asserts that the present invention lacks legally sufficient utility because the numerous utilities disclosed are not "substantial". In support of this contention, the Final Action discusses at length the proposition that because the function of the protein encoded by the claimed nucleic acid is not disclosed, the invention lacks a substantial utility. The touchstone of "substantial" utility is "real world" or "practical utility." *See, e.g., Fujikawa v. Wattanasin*, 93 F.3d 1559, 1563, 39 U.S.P.Q.2d 1895, 1899 (Fed. Cir. 1996). "'Practical utility' is a shorthand way of attributing "real world" value to claimed subject matter. In other words, one skilled in the art can use a claimed discovery in a manner which provides some immediate benefit to the public." *Nelson v. Bowler*, 626 F.2d 853, 856, 857, 206 U.S.P.Q. 881, 883 (CCPA 1980) ("tests evidencing pharmacological activity may manifest a practical utility even though they may not establish a specific therapeutic use").[6]

There can be no question that one skilled in the art can use the claimed nucleic acid molecules in a manner which provides an immediate benefit to the public, for example to detect the presence or absence of polymorphisms. The detection of polymorphisms provides an immediate benefit to the public because, *e.g.*, it enables a plant breeder to determine the distribution of parental genetic material in the progeny of a cross. This information about a plant's genetic profile, like the information about a compound's pharmacological profile in *Nelson*, provides an immediate benefit and thus a practical utility to the public.

Quite apart from the detection of polymorphisms, there is also no question that the public has recognized the benefits provided by the claimed subject matter, and has attributed "real world" value to such nucleic acid molecules. The utility of ESTs is not merely an academic issue; the real world value of ESTs is self-evident from the growth of a multi-million dollar

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[6] *Accord Cross v. Iizuka*, 753 F.2d 1040, 1050, 224 U.S.P.Q. 739, 747-48 (Fed. Cir. 1985); *Rey-Bellet v. Engelhardt*, 493 F.2d 1380, 1383, 181 U.S.P.Q. 453, 454 (CCPA 1974).

industry in the United States premised on the usefulness of ESTs. Like fermentation processes involving bacteria, ESTs and nucleic acid molecules with EST sequences are "industrial product[s] used in an industrial process – a useful or technical art if there ever was one." *In re Bergy*, 563 F.2d 1031, 1038, 195 U.S.P.Q. 344, 350 (CCPA 1977).

The market participants for EST products are primarily sophisticated corporations and highly knowledgeable scientists who are unlikely to pay for useless inventions. *Compare Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 960, 220 U.S.P.Q. 592, 599 (Fed. Cir. 1983) ("People rarely, if ever, appropriate useless inventions"). Quite simply, the commercial value of ESTs is proof of their real world value and of the benefits they provide to the public. This evidence cannot be ignored. The patent system was created to serve and foster growth and development in the industrial arts. If the industries themselves recognize and appreciate the value of an invention, it is not for the Patent Office to say that they are mistaken.

(3) The Disclosed Utilities Are Credible to One of Skill in the Art

An assertion of utility must be accepted by the Examiner unless it would not be considered "credible" by a person of ordinary skill in the art. MPEP § 706.03(a). Cases in which utility was found not to be credible are rare, and usually involve "hare-brained" utilities.[7] A challenge to the credibility of a utility is essentially a challenge directed to operability, and such a challenge must be supported by a clear statement of "factual reasons which would lead

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[7] Examples of incredible utilities are given in MPEP § 2107 at page 2100-33-34, and include:

> an invention asserted to change the taste of food using a magnetic field (*Fregeau v. Mossinghoff*, 776 F.2d 1034, 227 U.S.P.Q. 848 (Fed. Cir. 1985)), a perpetual motion machine (*Newman v. Quigg*, 877 F.2d 1575, 11 U.S.P.Q. 1340 (Fed. Cir. 1989)), a flying machine operating on "flapping or flutter function" (*In re Houghton*, 433 F.2d 820, 167 U.S.P.Q. 687 (C.C.P.A. 1970)), a method for increasing the energy output of fossil fuels upon combustion through exposure to a magnetic field (*In re Ruskin*, 354 F.2d 395, 148 U.S.P.Q. 221 (C.C.P.A. 1966)), uncharacterized compositions for curing a wide array of cancers (*In re Citron*, 325 F.2d 248, 139 U.S.P.Q. 516 (C.C.P.A. 1963)), a method of controlling the aging process (*In re Eltgroth*, 419 F.2d 918, 164 U.S.P.Q. 221 (C.C.P.A. 1970)), and a method of restoring hair growth (*In re Ferens*, 417 F.2d 1072, 163 U.S.P.Q. 609 (C.C.P.A. 1969)).

one skilled in the art to question the objective truth of the statement of operability." *In re Gaubert*, 524 F.2d 1222, 1225-26, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975); *see In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995); MPEP § 706.03(a).

Applicants have explicitly identified specific and substantial utilities, not only in the specification, but in Applicants' Response dated November 27, 2001 at pages 7-8. "To violate [35 U.S.C.] 101 the claimed device must be totally incapable of achieving a useful result." *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571, 24 U.S.P.Q.2d 1401, 1412 (Fed. Cir. 1992). To date, the Examiner has provided no evidence that the claimed nucleic acid molecules will not work for the disclosed utilities. Unless and until the Examiner can prove that the claimed invention is wholly inoperative, the rejection must be withdrawn.

In view of the above, Applicants contend that the claimed nucleic acid molecules are supported by credible, specific, and substantial utilities disclosed in the specification. Moreover, the Examiner has failed to raise any credible evidence challenging the presently asserted utilities. Consequently, the rejection of claim 1 under 35 U.S.C. §101 is improper and should be reversed.

C. The Claimed Nucleic Acids Are Enabled by the Specification

The enablement of the claimed nucleic acid molecule, transformed plants incorporating the nucleic acid molecule, and methods of using the claimed nucleic acid molecule have also been challenged. Claims 1 and 4-12 were erroneously rejected under 35 U.S.C. § 112, first paragraph as allegedly not enabled by the specification, because the claimed nucleic acid molecule, transformed plants, and methods allegedly lack utility and therefore cannot be enabled. *Final Action* at page 6. This rejection has been overcome by the arguments stated above regarding utility because it is well-established law that "the enablement requirement is met if the description enables any mode of making and using the invention." *Johns Hopkins University v. CellPro*, 152 F.3d 1342, 1361, 47 U.S.P.Q.2d 1705, 1719 (Fed. Cir. 1998) (emphasis added), *quoting Engel Indus. v. Lockformer Co.*, 946 F.2d 1528, 1533, 20 U.S.P.Q.2d 1300, 1304 (Fed.

Cir. 1991). Unless and until the Examiner comes forth with evidence to rebut the objective truth of the utilities disclosed in the specification, this enablement rejection is improper and should be reversed.

D. The Specification Provides An Adequate Written Description of the Claimed Invention

Pending claims 1 and 4-12 were also erroneously rejected under 35 U.S.C. § 112, first paragraph as allegedly not being supported by an adequate written description. The Examiner acknowledges that SEQ ID NO: 1 meets the written description requirement, however, in support of this rejection, the Examiner asserts that "the specification provides insufficient written description to support the genus encompassed by the claim." *Final Action* at pages 6-7.

"A description as filed is presumed to be adequate, unless and until sufficient evidence or reasoning to the contrary has been presented by the examiner to rebut the presumption." *Federal Register* 66(4):1107, Written Description Guidelines (2001). The Examiner is required to disclose "express findings of fact which support the lack of written description conclusion." *Id.* In the present case, the Examiner presents no findings of fact to rebut the presumption that the written description in the specification is adequate. The only fact alleged by the Examiner in support of the written description rejection is that the claims encompass a sequence that is less than a full-length cDNA, and thus the sequences do not meet the written description requirement. *Final Action* at pages 6-7. Whether the claimed nucleic acid molecule is a full-length cDNA is irrelevant to the question of whether nucleic acid molecules comprising the nucleic acid sequence of SEQ ID NO: 1 are sufficiently described by the present specification.

(1) The Specification Reflects Applicants' Possession of the Claimed Invention

The purpose of the written description requirement is to ensure that the inventors had possession of the claimed subject matter, *i.e.*, to ensure that the inventors actually invented what

is claimed. *Gentry Gallery Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *Lockwood v. American Airlines*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997); *In re Alton*, 76 F.3d 1168, 1172, 37 U.S.P.Q.2d 1578, 1581 (Fed. Cir. 1996). If a person of ordinary skill in the art would, after reading the specification, understand that the inventors had possession of the claimed invention, even if every nuance of the invention was not expressly described, then the written description requirement has been met. *In re Alton*, 76 F.3d at 1175, 37 U.S.P.Q.2d at 1584.

A person of ordinary skill in the art, *e.g.*, a molecular biologist, would, after reading the present specification, understand that Applicants had possession of SEQ ID NO: 1, plants transformed by SEQ ID NO:1, and methods incorporating SEQ ID NO:1 and therefore, possession of the claimed invention. Claims "may be broader than the specific embodiment disclosed in a specification." *Ralston Purina Co. v. Far-mor-Co*, 772 F.2d 1570, 1575, 227 U.S.P.Q. 177, 179 (Fed. Cir. 1985) (*quoting In re Rasmussen*, 650 F.2d 1212, 1215, 211 U.S.P.Q. 323, 326 (CCPA. 1981)). Thus, simply because the claim at issue is intended to cover molecules that include the recited sequence joined with additional sequences does not mean that Applicants were any less in possession of the claimed nucleic acid molecules.

The use of open claiming language (comprising) or semi-open claiming (consisting essentially of) does not alter the fact that a skilled artisan would readily envision adequate written description support for the claimed invention. It is well-established that use of the transitional term "comprising" leaves the claims "open for the inclusion of unspecified ingredients even in major amounts." *Ex parte Davis*, 80 U.S.P.Q. 448, 450 (B.P.A.I. 1948). *Accord PPG Indus. v. Guardian Indus.*, 156 F.3d 1351, 1354, 48 U.S.P.Q.2d 1351, 1353-54 (Fed. Cir. 1998); *Moleculon Research Corp. v. CBS*, 793 F.2d 1261, 1271, 229 U.S.P.Q. 805, 812 (Fed. Cir. 1986). The fact that the claims at issue are intended to cover molecules that include the recited sequences joined with additional sequences does not mean that Applicants

were any less in possession of the claimed nucleic acid molecules.[8] Applicants have reasonably conveyed possession of the claimed invention to one skilled in the art, even when additional sequences are added to either end.

Indeed, the present application describes more than just the nucleotide sequence required by the claims (SEQ ID NO: 1). For example, it describes vectors comprising the claimed nucleic acid molecules. *Specification* at page 56, line 15 through page 66, line 11 and describes how to make the nucleotide sequences and the libraries from which they were originally purified. *See* specification at page 1, line 16 through page 4, line 23, and Examples 1-2. Furthermore, the addition of extra nucleotides or detectable labels to the claimed nucleotide sequence (SEQ ID NO: 1) is readily envisioned by one of ordinary skill in the art upon reading the present specification.[9] *See, e.g., Specification* at page 20, lines 10-14 (describing sequences with labels to facilitate detection), page 26, line 1 through page 27, line 3 (describing fusion nucleic acid molecules), page 4, lines 9-23 (describing automated nucleic acid synthesizers that can be used to build nucleic acid molecules), and page 80, lines 4-12 (citing references describing the construction, manipulation and isolation of nucleic acid macromolecules).

(2) Applicants Have Described the Claimed Invention

As mentioned above, the Examiner alleges that "[t]he specification provides insufficient written description to support the genus encompassed by the claim." *Final Action* at page 7. Relying on *Fiers v. Revel*, 984 F.2d 1164, 25 U.S.P.Q.2d 1601 (Fed. Cir. 1993), the Examiner

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[8] If the Examiner is arguing that no possession is shown because the precise claim language is not used in the specification, then it goes beyond what is required by the law. It is well-settled that the description of a claimed invention need not be *in ipsis verbis*. *Gentry Gallery v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *In re Alton*, 76 F.3d 1168, 1175, 37 U.S.P.Q.2d 1578, 1583 (Fed. Cir. 1996); *Martin v. Johnson*, 454 F.2d 746, 751, 172 U.S.P.Q. 391, 395 (C.C.P.A. 1972).

[9] It is established patent jurisprudence that Applicants need not teach "conventional and well-known genetic engineering techniques." *E.g., Ajinomoto Co. v. Archer-Daniels-Midland Co.*, 228 F.3d 1338, 1345, 56 U.S.P.Q.2d 1332, 1337 (Fed. Cir. 2000).

states that "[a]dequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required." *Final Action* at page 7. In this regard, unlike the appellant in *Fiers*, Applicants have indeed provided a chemical structure for the claimed nucleic acid itself, *i.e.*, SEQ ID NO: 1.

Moreover, each nucleic acid molecule within a claimed genus does not need to be described by its complete structure. The Federal Circuit has elucidated a test for written description wherein a genus of nucleic acids may be described by a structural feature that distinguishes members of the claimed genus from non-members of the claimed genus. *Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568-69, 43 U.S.P.Q.2d 1398, 1406 (Fed. Cir. 1997). In contrast to the mere name "cDNA" provided in *Eli Lilly*, Applicants have provided a detailed chemical structure by way of the claimed SEQ ID NO: 1. Applicants have therefore satisfied the *Eli Lilly* test for written description.

The claimed nucleic acid molecule, transformed plant incorporating the nucleic acid molecule, and methods of using the nucleic acid molecule are a genus of nucleic acid molecules, constructs, and methods having a common structural feature of a particular enumerated nucleotide sequence, *i.e.*, SEQ ID NO: 1. The respective common structural feature (the nucleotide sequence) is shared by every nucleic acid molecule in the claimed genus, and it distinguishes the members of the claimed genus from non-members. For example, if a nucleic acid molecule such as an mRNA contains the nucleotide sequence of SEQ ID NO: 1, then it is a member of the claimed genus of nucleic acid molecules comprising a nucleic acid sequence of SEQ ID NO: 1. If a nucleic acid molecule does not contain SEQ ID NO: 1, then it is not a member of that claimed genus. The presence of other nucleotides at either end of the recited sequence will not interfere with the recognition of a claimed nucleic acid molecule as such – it

either contains the nucleotides of SEQ ID NO: 1 or it does not. [10] One skilled in the art would clearly know if a nucleic acid molecule contains one of the recited nucleotide sequences.

In sum, because the specification demonstrates that Applicants had possession of the invention, and have provided an adequate description of the claimed genus of nucleic acid molecules, transformed plants incorporating the genus of nucleic acid molecules, and methods of using the genus of nucleic acid molecules the specification satisfies the written description requirement of 35 U.S.C. § 112, first paragraph, and the rejection should be reversed.

[10] The same argument applies to each of the other genera, for example, if a transformed plant contains the nucleotide sequence of SEQ ID NO: 1, then it is a member of the claimed genus of transformed plants incorporating nucleic acid molecules comprising a nucleic acid sequence of SEQ ID NO: 1.

CONCLUSION

In view of the foregoing, it is respectfully requested that the Board of Patent Appeals and Interferences reverse the Rejections and that the subject application be allowed forthwith.

Respectfully submitted,

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APPENDIX A
Pending Claims

1. A substantially purified nucleic acid molecule comprising the nucleic acid sequence of SEQ ID NO: 1.

4. A transformed plant having a nucleic acid molecule which comprises:

   (a) an exogenous promoter region which functions in a plant cell to cause the production of an mRNA molecule;

   (b) a structural nucleic acid molecule comprising a nucleic acid sequence selected from the group consisting of SEQ ID NO: 1 and complement thereof; and

   (c) a 3' non-translated sequence that functions in said plant cell to cause termination of transcription and addition of polyadenylated ribonucleotides to a 3' end of said mRNA molecule.

5. The transformed plant according to claim 4, wherein said structural nucleic acid molecule is a complement of the nucleic acid sequence of SEQ ID NO: 1.

6. The transformed plant according to claim 5, wherein said plant is soybean or maize.

7. The transformed plant according to claim 5, wherein said plant is soybean.

8. A method for determining a level or pattern in a plant cell or plant tissue of a protein in a plant comprising:

   (a) incubating, under conditions permitting nucleic acid hybridization, a marker nucleic acid molecule, said marker nucleic acid molecule selected from the group of marker nucleic acid molecules which specifically hybridize to a nucleic acid

molecule having the nucleic acid sequence selected from the group consisting of SEQ ID NO: 1 or complement thereof, with a complementary nucleic acid molecule obtained from said plant cell or plant tissue, wherein nucleic acid hybridization between said marker nucleic acid molecule and said complementary nucleic acid molecule obtained from said plant cell or plant tissue permits the detection of an mRNA for said protein;

(b) permitting hybridization between said marker nucleic acid molecule and said complementary nucleic acid molecule obtained from said plant cell or plant tissue; and

(c) detecting the level or pattern of said complementary nucleic acid, wherein the detection of said complementary nucleic acid is predictive of the level or pattern of said protein.

9. The method of claim 8, wherein said level or pattern is detected by *in situ* hybridization.

10. The method of claim 8, wherein said level or pattern is detected by tissue printing.

11. The method of claim 8, wherein said plant is maize or soybean.

12. The method of claim 11, wherein said plant is soybean.